



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-D-0395]

Clinical Study Designs for Surgical Ablation Devices for Treatment of Atrial Fibrillation;  
Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled “Clinical Study Designs for Surgical Ablation Devices for Treatment of Atrial Fibrillation.” This guidance provides FDA’s recommendations on clinical trial designs for surgical ablation devices intended for the treatment of atrial fibrillation.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled “Clinical Study Designs for Surgical Ablation Devices for Treatment of Atrial Fibrillation” to the Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-847-8149. See the

SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Libet Garber,  
Center for Devices and Radiological Health,  
Food and Drug Administration,  
10903 New Hampshire Ave.,  
Bldg. 66, rm. 1254,  
Silver Spring, MD 20993-0002,  
301-796-6912.

SUPPLEMENTARY INFORMATION:

I. Background

Atrial fibrillation (AF) is a complex arrhythmia of the heart. This guidance describes elements of suggested clinical study design for surgical ablation devices used to treat patients with longstanding persistent AF and patients with symptomatic paroxysmal AF, such as inclusion and exclusion criteria and assessment of effectiveness, which may differ for these patient populations. In the Federal Register of September 14, 2009 (74 FR 46996), FDA announced the availability of the draft guidance document. Interested persons were invited to comment by December 14, 2009. Three sets of comments were received with recommendations related to definitions and certain elements of the recommended study design(s), such as study endpoints, endpoint assessments, appropriate control groups, and followup of study subjects. In

response, FDA revised the guidance document to address the comments and clarify our recommendations as appropriate. This guidance supersedes the draft guidance entitled “Clinical Study Designs for Surgical Ablation Devices for Treatment of Atrial Fibrillation,” dated September 14, 2009.

## II. Significance of Guidance

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency’s current thinking on clinical study designs for surgical ablation devices for treatment of atrial fibrillation. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

## III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov>. To receive “Clinical Study Designs for Surgical Ablation Devices for Treatment of Atrial Fibrillation,” you may either send an email request to [dsmica@fda.hhs.gov](mailto:dsmica@fda.hhs.gov) to receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1708 to identify the guidance you are requesting.

## IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management

and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 812 have been approved under OMB control number 0910-0078; the collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910-0120; the collections of information in 21 CFR parts 50 and 56 have been approved under OMB control number 0910-0130; and the collections of information under 21 CFR part 814 have been approved under OMB control number 0910-0231.

#### V. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see ADDRESSES) or electronic comments to <http://www.regulations.gov>. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Dated: February 11, 2013.

Leslie Kux,

Assistant Commissioner for Policy.